

Section II (Amendments to the Claims)

Please amend claims 20, 35, 41, 43, 44, 46, 47, 50, and 52-56, cancel claims 33, 34, 36-40, and add new claims 57-73 as set out below.

I-19. (Canceled)**20. (Currently amended) A gastric occlusive device, comprising:**

a balloon formed from two substantially hemispherical vacuum thermoformed half-sections of a multilayer film comprising: (A) a layer of sealing film, having main top and bottom surfaces; and (B) [[a]] at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the layer(s) at least one layer of thermoplastic polymer film alone lacks such gas barrier character, wherein the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and

an effervescent material contained in said balloon, said effervescent material being and arranged for contact with introduced liquid reactive with the effervescent material to liberate gas for inflation of the balloon, wherein said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils.

21. (Original) The gastric occlusive device of claim 20, wherein the thermoplastic polymer film comprises a thermoplastic polymer selected from the group consisting of polyurethane elastomers, polyester ether elastomers, polyamide elastomers, polyamides, styrenic elastomers, polyvinylchloride, polyvinylethers, ethylene vinyl acetate, polyethylene, polyethylene copolymers, polypropylene copolymers, and combinations of two or more of the foregoing, and wherein when the multilayer film comprises more than one layer of thermoplastic polymer film, each of such layers may be compositionally the same as or different from other layers of thermoplastic polymeric material.

4179-128

22. **(Original)** The gastric occlusive device of claim 20, wherein the sealing film comprises a material selected from the group consisting of polyvinylidene chloride (PVDC), polyvinylidene bromide, and ethylene vinyl alcohol polymers.

23. **(Original)** The gastric occlusive device of claim 20, wherein the thermoplastic polymer film comprises a thermoplastic polymer selected from the group consisting of polyurethane and polyurethane co-polymers.

24. **(Original)** The gastric occlusive device of claim 20, wherein the sealing film comprises a material selected from the group consisting of polyvinylidene chloride and EVOH.

25. **(Original)** The gastric occlusive device of claim 20, wherein the thermoplastic polymer film is formed of polyurethane or a polyurethane co-polymer.

26. **(Original)** The gastric occlusive device of claim 20, wherein the sealing film comprises polyvinylidene chloride.

27. **(Previously presented)** The gastric occlusive device of claim 20, wherein the multilayer film comprises up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers.

28. **(Previously presented)** The gastric occlusive device of claim 20, wherein the multilayer film has a thickness in a range of from about 0.5 to 10 mils (0.0127 mm to 0.254 mm).

29. **(Original)** The gastric occlusive device of claim 20, wherein the multilayer film has a thickness in a range of from about 2 mils to about 6 mils (0.0508 mm to 0.1524 mm).

30. **(Original)** The gastric occlusive device of claim 20, wherein the thickness of the sealing film is in a range of from about 0.2 mil to about 6 mil (0.00508 mm to 0.1524 mm).

31. **(Previously presented)** The gastric occlusive device of claim 20, wherein the thermoplastic

4179-128

polymer film has a thickness in a range of from about 2.0 mils to about 5.0 mils (0.0508 mm to 0.127 mm).

32. (Original) The gastric occlusive device of claim 20, comprising a sealing film of polyvinylidene chloride, having a thickness in a range of from about 0.25 to about 2.0 mil (0.00635 mm to 0.0508 mm), to which a polyurethane elastomer film, having a thickness in a range of from about 2.0 mils to about 5.0 mils (0.0508 mm to 0.127 mm), is extrusion bonded.

33. (Cancelled) ~~The gastric occlusive device of claim 20, wherein two pieces of multilayer film are bonded to one another.~~

34. (Cancelled) ~~The gastric occlusive device of claim 20, wherein two half sections of multilayer film are thermoformed, and then bonded to one another.~~

35. (Currently amended) The gastric occlusive device of claim 20, wherein two half-sections ~~pieces of multilayer film~~ are bonded circumferentially to one another such that the peripheral seam forms to form a 360° seal having a and the peripheral seam is devoid of any neck or opening therein.

36. (Cancelled)

37. (Cancelled)

38. (Cancelled)

39. (Cancelled)

40. (Cancelled)

41. (Currently amended) A gastric occlusive balloon adapted to be inflated by an inflation medium in a gastric cavity of a subject for treatment of said subject, said balloon being formed ~~from two substantially hemispherical vacuum thermoformed half-sections of including a film-~~

4179-128

providing a seal that is degradable in exposure to physiological components in said gastric cavity, said film being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said subject and to deflate after said period of time by egress of said inflation medium through the film, said film comprising a multilayer film including: (A) a layer of sealing film, having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character; wherein;

the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam;

at least a portion of said balloon comprises a degradable seal material that is degradable in exposure to physiological components in said gastric cavity, said degradable seal material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said subject and to deflate after said period of time by egress of said inflation medium through the degradable seal material; and

said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils.

42. (Cancelled)

43. (Currently amended) The gastric occlusive balloon of claim 41, wherein said film degradable seal material comprises a thermoplastic material.

44. (Currently amended) The gastric occlusive balloon of claim 43, wherein said thermoplastic material comprises [[the]] a material selected from the group consisting of polyurethane, polyester, and polyamide.

45. (Previously presented) The gastric occlusive balloon of claim 43, wherein said thermoplastic material comprises a material selected from the group consisting of polyethylene, polypropylene, polyvinyl chloride, polyvinylether, ethylene vinyl acetate, and combinations of two or more of the foregoing.

4179-128

46. (Currently amended) The gastric occlusive balloon of claim 41, wherein said film degradable seal material comprises a material selected from the group consisting of polyvinylidene chloride, polyvinylidene bromide, and ethylene vinyl alcohol polymers.

47. (Currently amended) The gastric occlusive balloon of claim 41, wherein said film degradable seal material comprises polyvinylidene chloride, and polyurethane.

48. (Previously presented) The gastric occlusive balloon of claim 41, wherein the balloon contains an inflation gas-generating reactant.

49. (Previously presented) The gastric occlusive balloon of claim 48, wherein said inflation gas-generating reactant in the presence of water or moisture reacts to form CO₂ gas.

50. (Currently amended) The gastric occlusive balloon of claim 41, wherein the multilayer film comprises up to 4 thermoplastic polymer film layers, optionally with adhesive between the sealing film and any of the thermoplastic polymer film layers.

51. (Previously presented) The gastric occlusive balloon of claim 41, wherein said balloon is adapted to be inflated by a gas supply tube when the balloon is disposed in the gastric cavity of said subject.

52. (Currently amended) The gastric occlusive balloon of claim 41, wherein said film includes a seam therein the peripheral seam forms a 360° seal and the peripheral seam is devoid of any neck or opening therein.

53. (Currently amended) The gastric occlusive balloon of claim 52, wherein said peripheral seam comprises an RF welded seam.

54. (Currently amended) The gastric occlusive balloon of claim 41, wherein said film comprises a degradable seal material comprises formed of an ethylene vinyl

4179-128

acetate/hydroxycellulose material that is progressively degradable in the gastric cavity to create an opening in the balloon for deflation of said balloon.

55. (Currently amended) A gastric occlusive balloon adapted to be inflated by an inflation medium in a gastric cavity of a subject for treatment of said subject, said balloon including being formed from two substantially hemispherical vacuum thermoformed half-sections of a multilayer film providing a seal that is degradable in exposure to physiological components in said gastric cavity, said multilayer film being adapted to retain the balloon in an inflated state for a period of time sufficient for said treatment of said subject and to deflate after said predetermined period of time by egress of said inflation medium through the multilayer film, wherein the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam, wherein said balloon is generally spherical in shape, wherein said film is a multilayer film has having a thickness of up to 10 mils and includes at least one up-to-4 thermoplastic polymer film layer layers, optionally with adhesive between a sealing film and at least one thermoplastic polymer film layer layers, and wherein said multilayer film comprises (i) a layer of polyvinylidene chloride or EVOH polymer having a thickness of from about 0.25 to about 2.0 mils (0.00635 mm to 0.0508 mm), and (ii) a layer of polyurethane having a thickness of from about 2.0 to about 5.0 mils (0.0508 mm to 0.127 mm), and wherein said balloon has a diameter when inflated in a range of from 3 to 5 inches.

56. (Currently amended) The gastric occlusive device of claim 20, wherein two pieces of multilayer film are bonded circumferentially to one another to form the peripheral seam forms a 360° seal and the peripheral seam is devoid of any having a seam with a neck or opening therein.

57. (New) The gastric occlusive device of claim 20, wherein the effervescent material is secured along an inner surface of the balloon.

58. (New) The gastric occlusive device of claim 57, wherein the effervescent material is substantially centrally located along one half-section, with the effervescent material having a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections.

4179-128

59. (New) The gastric occlusive device of claim 20, wherein the sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer, said at least one layer of thermoplastic polymer film comprises a first and a second layer of polyurethane, said first layer of polyurethane is laminated to the sealing film along both the main top surface thereof, and said second layer of polyurethane is laminated to the sealing film along the main bottom surface thereof.

60. (New) The gastric occlusive balloon of claim 41, wherein the degradable material comprises the multilayer film.

61. (New) The gastric occlusive balloon of claim 41, further comprising an effervescent material disposed along an inner surface of the balloon, and the effervescent material is substantially centrally located along one half-section, with the effervescent material having a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections.

62. (New) The gastric occlusive balloon material of claim 41, further comprising a self-healing seal valve adapted to permit the introduction of a liquid or aqueous substance into the balloon and retain said introduced liquid or aqueous substance within said balloon.

63. (New) The gastric occlusive balloon of claim 55, further comprising an effervescent material disposed along an inner surface of the balloon, and the effervescent material is substantially centrally located along one half-section, with the effervescent material having a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections.

64. (New) A gastric occlusive device, comprising:

a balloon formed from two substantially hemispherical vacuum thermoformed half-sections of a multilayer film, the multilayer film comprising a layer of sealing film laminated between a first and a second layer of thermoplastic polymer film, wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film, the first and second thermoplastic polymer film layers independently lack such gas barrier character, and the

4179-128

vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and

an effervescent material disposed within the balloon, the effervescent material being arranged for contact with an introduced liquid adapted to react with the effervescent material to liberate gas for inflation of the balloon.

65. (New) The gastric occlusive device of claim 64, wherein the sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer, and the thermoplastic polymeric film comprises any of polyurethane and a polyurethane co-polymer.

66. (New) The gastric occlusive device of claim 64, further comprising an adhesive disposed between any of (1) the layer of sealing film and the first layer of thermoplastic material; and (2) the layer of sealing film and the second layer of thermoplastic material.

67. (New) The gastric occlusive device of claim 64, wherein the multilayer film has a thickness of up to 10 mils.

68. (New) The gastric occlusive device of claim 64, wherein the balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches.

69. (New) The gastric occlusive device of claim 64, wherein the effervescent material is secured along an inner surface of the balloon.

70. (New) The gastric occlusive device of claim 64, wherein the effervescent material is substantially centrally located along one half-section, with the effervescent material having a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections.

71. (New) The gastric occlusive device of claim 64, further comprising a self-healing seal valve adapted to permit the introduction of a liquid or aqueous substance into the balloon and retain said introduced liquid or aqueous substance within said balloon.

4179-128

72. (New) The gastric occlusive device of claim 64, further comprising a film material providing a seal that is degradable in exposure to physiological components in said gastric cavity, said film being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said subject and to deflate after said period of time by egress of said inflation medium through the film.

73. (New) The gastric occlusive device of claim 64, further comprising a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent.